WV Board of Pharmacy

FAQ WV BOP for COVID-19 (updated 8/28/2020)

These waivers will CEASE to be in effect when the WV State of Emergency related to the COVID-19 pandemic ends.

1. Are the limitations on dispensing of hydroxychloroquine from March 2020 still in place?

No. The WV BOP has voted 8/25/2020 to rescind the Emergency Rule limiting the quantity allowed for hydroxychloroquine. The drug has been removed from the FDA Drug Shortage list. For information regarding the latest study results on the use of hydroxychloroquine in COVID-19 and other therapies being tested for its treatment, a summary table can be found for FREE at <u>ASHP Assessment of Evidence for COVID-19-related Treatments.</u>

2. Can a pharmacist provide emergency refills of a life sustaining medication?

Yes. This is current law and does not require a waiver. According to §30-5-36. Emergency prescriptions for life-sustaining medication. The pharmacist may provide a 30 day supply or standard unit of dispensing of life sustaining medication or therapy for a chronic condition under the stipulations of 30-5-36. Schedule III-V are limited to 72 hour supply. Details can be found on page 39 of the 2019 electronic WV law book.

3. If the patient has a prescription for 30 days with 2 RF, can this be converted to a 90 day supply?

Yes. This is current law and does not require a waiver. According to §30-5-35. Conversion of prescriptions authorizing refills. The pharmacist may convert a 30 day supply of medication with 2 refills remaining to a 90 day supply under the stipulations of 30-5-35. Details can be found on page 38 of the 2019 electronic WV law book.

4. Can my pharmacy use remote processing of prescriptions for social distancing?

Yes. Due to the WV State of Emergency, the WV BOP has adopted the following guidance to permit licensed pharmacy professionals (pharmacists, pharmacy interns, and pharmacy technicians/pharmacy technician trainees) to process prescriptions and medication orders from remote locations. This guidance is being adopted based on §15-14-4, §15-15-7.7, and §15-1-24.

For the purpose of this guidance, "remote processing" is defined as the processing of a medication order or prescription for a WV pharmacy from a location other than the physical licensed pharmacy.

An additional frequently asked questions document for this topic will be placed on the WV BOP Website ASAP.

For pharmacists, remote processing does not include the dispensing of a drug, but may include receiving, interpreting, evaluating, clarifying, and approval of medication orders and prescriptions. Additionally, remote processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. A pharmacist at all settings must hold the physical product in hand to do the physical product final check. This does not change current procedure at rural access facilities.

For pharmacy technicians, registered pharmacy technicians, technician trainees, and pharmacy interns, remote processing does not include the dispensing of a drug, but may include prescription or order entry, other data entry, insurance processing, and clarifying prescriptions and medication orders.

Provided that the pharmacies/pharmacists: have computer software and hardware that is adequate for the task being performed, steps are taken to safeguard protected health information and the Board is notified (approval not necessary).

5. Can I, as the pharmacist, permit a patient to get his/her controlled substance medication filled early?

Yes. WV law prohibits early refills on controlled substances no more than 3 days early per §15-2-8.15. Refilling of Schedule III or IV prescriptions. The WV BOP guidance is that the pharmacist may dispense the refill early using his or her professional judgement and shall document the reason for the early refill.

6. With exposure to COVID-19 and suspected illness, it is necessary for to exceed the pharmacy technician to pharmacist ratio. Is this at all possible?

Yes. Per §15-7-5.3. A ratio of no more than four pharmacy technicians and/or pharmacy technician trainees per on-duty pharmacist operating in any pharmacy shall be maintained. This ratio shall not include pharmacy interns. During the COVID-19 WV State of Emergency, only if exceeding the ratio is due to actual impact of COVID-19 virus directly on the pharmacy, facility or staff involved, the pharmacy may exceed the ratio of 4 to 1. If the pharmacy will exceed the ratio for more than 2 days, the Board must be notified at boardofpharmacy@wv.gov.

7. I am not currently licensed in WV, but I do hold a current, active, non-restricted license (pharmacist, technician, intern) in another state. Can I come to help in WV?

West Virginia Code 30-5-6(5) gives the Board the authority to "determine the qualifications of any applicant for a license, <u>permit</u>, and registration. The WV BOP will allow a pharmacist, pharmacy intern, or pharmacy technician to work in WV with a temporary permit.

The "temporary permit" is defined as a limited, legal authorization issued by the board to a pharmacist, pharmacy technician, or pharmacy intern in this state while serving under special circumstances of public need after having demonstrated he/she has identification to verify current unrestricted licensure in another state.

> Passport as a pre-requisite for a temporary or emergency license

Pharmacists and Pharmacy Technicians who are seeking temporary or emergency license with West Virginia must first obtain an NABP Passport. The NABP Passport is a license verification process administered by the National Association of Boards of Pharmacy to assist in the COVID-19 pandemic response.

Individuals can obtain an NABP Passport by logging into their NABP e-Profile at https://dashboard.nabp.pharmacy/Login/Splash, clicking 'customer', then 'my e-Profile', and then click on the tile labeled: "NABP Passport/COVID-19 Emergency". Please follow the "add a state" instructions on this page. Once complete, click submit.

Please note, your license information must be up to date including expiration date and license status. Licensure information will be reviewed and approved by NABP and will be sent to the Board for review and issuance of the temporary license. Individuals are only approved to practice after receipt of the state-issued temporary license. Licensees will also be notified on their e-Profile and via email.

Once you have received your NABP Passport approval, come back to the WV BOP website at https://www.wvbop.com/practitioners/temp/application/person.asp, complete the application information and upload your NABP Passport.

8. What should my pharmacy do if PPE is limited and we must do sterile compounding?

In anticipation of possible shortages of masks, USP supports appropriate risk-based enforcement discretion during the COVID-19 pandemic, in the interest of conserving garbing and personal protective equipment. FDA has also issued a statement regarding conservation strategies.

Therefore, pharmacists may implement a process for reusing masks in a manner that does not compromise the microbial state of control in cleanrooms. The user should visibly inspect the product prior to use and, if there are concerns (such as degraded materials or visible tears), discard the product.

- A policy and procedure should clearly indicate how an employee's reused mask will be identified, stored, and under what conditions it may no longer be used.
- Garb (gowns and masks) for non-hazardous drug compounding may be reused in accordance with facility standard operating procedures. Gowns must be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing).
- Soiled, contaminated, torn, or punctured garb must be changed immediately and not re-used.
- Be aware that counterfeit masks and gowns may be on the market, especially during this time of reduced supply.
- Weekly surface sampling inside ISO 5 space must be performed when garbing in a manner that is not consistent with USP requirements.
- Refer to:
 - CDC's Interim Guidance on preventing COVID-19 from spreading, which includes Strategies for Optimizing the Supply of N95 Respirators https://www.cdc.gov/coronavirus/2019ncov/hcp/respirators-strategy/
 - o *Healthcare Supply of Personal Protective Equipment* and https://www.cdc.gov/coronavirus/2019-ncov/hcp/healthcare-supply-ppe-index.html
 - FDA's Surgical Mask and Gown Conservation Strategies Letter to Healthcare Providers at https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers
 - USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Sterile Compounding During COVID-19 Pandemic https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-garb-and-ppe.pdf

An additional resource for information for up-to-date information on sterile compounding is the CriticalPoint Peer Network. We would suggest to subscribe to the Silver level which is free and you can see the latest webinars, recommendations and other material. This should be done ASAP because CriticalPoint will continually monitor the situation and make updates. https://peernetwork.criticalpoint.info/

9. What if my pharmacy is closed? Do I still need to submit CSMP reports?

Per §15-8-4.1 a pharmacy or dispenser of controlled substances is required to report a daily "zero" report if there are no dispensings. The WV BOP waive the requirement to submit reports of "zero" when the pharmacy is closed due to COVID-19 during the state of emergency. The notice that the pharmacy is closed will serve as the notice for this, also.

10. I am not going to have my 6 live continuing education hours required to renew my pharmacy license. What am I supposed to do?

Rule:

1. §15-3-4.3 Six (6) hours of the thirty (30) CPE hours required every two (2) years shall be obtained through a live presentation requiring the physical presence of the pharmacist at the CPE program.

- 2. §15-3-4.4 3 hrs Drug diversion requirement
- 3. §15-12-4.1.c basic life-support training for immunization renewal

The WV BOP anticipates completing online renewals as usual this renewal season. Because of the COVID-19 emergency pharmacists who have not met the 6 hours live CE requirement or 3 hour drug diversion requirement are expected to renew on time as usual, however, note that they are missing the live CE or drug diversion requirement. The WV BOP determined today to grant everyone missing those two requirements, OR the CPR immunization requirement, 90 days after the END of the WV State of Emergency to complete the necessary licensure requirements. It is vital that the <u>renewal</u> be completed on time for the waiver of live hours, drug diversion or CPR to be utilized. Failure to renew on time will result in the pharmacist license being inactive.

11. We have reached influenza vaccine season and my CPR card is expired, but there are no live classes being taught. What should I do?

The WV BOP determined at the beginning of the COVID-19 emergency to grant everyone missing those live CE, OR the CPR immunization requirement, 90 days after the END of the WV State of Emergency to complete the necessary licensure requirements. If you are going to be providing immunizations this fall, it is strongly recommended that you review the appropriate steps for CPR should you have an emergency and need to use the skill.

12. My pharmacy must close due to staffing issues and illness. What do I need to do?

Post notifications of the closure on the doors, website, social media, etc. In the event that a pharmacy must close due to illness or staff shortages, the pharmacy must notify the WV BOP within 48 hours at krista.d.capehart@wv.gov.

13. My pharmacy fills numerous prescriptions for Office-Based treatment Programs. Have there been any new rules for them?

Yes. These are posted on the WV BOP website at Opioid Treatment Program Providers Emergency Rule.

14. I have a patient who comes in to pick up their controlled substance and the driver's license is expired. Can the prescription medication be released?

Because a controlled substance prescription requires a valid government-issued identification, it is important for pharmacies to be aware of the action taken by the WV Division of Motor Vehicles.

The DMV is extending the expiration date of any driver's license, instructional permit, or vehicle registration with an expiration date in March or April of 2020 until September 30, 2020.

Utilize this "new" expiration date when assisting patients during this State of Emergency.

15. How should I keep my pharmacy staff and patients safe?

The WV BOP strongly recommends pharmacies implement strategies to ensure the safety of the pharmacy professionals and patients including the items listed below:

OSHA has provided recommendations specifically for retail pharmacies available <u>here.</u>

CDC Guidance for Pharmacies in community pharmacies is available <u>here</u>.

<u>Remember:</u> Governor Justice signed the statewide indoor face covering requirement to include that a face covering must be worn in all public indoor places where social distancing cannot be maintained. This does not apply to children under age 9 or anyone who has trouble breathing or otherwise is unable to remove the mask without assistance.

16. I have a patient requesting an immunization. Can I provide the immunization?

The CDC has provided updated <u>Guidance on the provision of vaccination during a pandemic</u>. This Guidance includes important information including recognizing that vaccination is an essential preventative care service during the pandemic, screening of patients for COVID-19 symptoms and defer vaccination if symptoms are present, the importance of personal protective equipment, and other considerations.

17. I heard about the US Dept of Health and Human Services has issues an order that allows pharmacists to vaccinate children ages 3 and up. Is this allowed in WV?

The WV BOP position statement is being sent out with this FAQ document regarding this question and can be found on the BOP website here.

18. I heard that there have been changes to Schedule II prescribing in WV. Can you summarize what those changes have been?

On March 31, 2020 Governor Justice waived the requirement that for chronic pain patients there must be an inperson physical examination every 90 days prior to prescribing a refill for a Schedule II opioid medication to an existing patient for chronic pain treatment (WV Code §16-54-4(h)) provided that the provider utilizes other appropriate tools to evaluate the patient at these intervals, and assesses whether continuing the course of treatment would be safe and effective for the patient.

On March 30, 3030 the DEA provided the Guidance allowing two exceptions enabling greater flexibility for oral Schedule II prescribing. However, because WV rules contain the same language, before the DEA exceptions could be enacted, WV emergency rules had to be filed permitting the same exceptions. The exceptions are to §15-1-17.1.6.c and §15-2-8.9.2 and are as follows:

- 8.9.2. In the case of an emergency situation, a practitioner may communicate a prescription for a Schedule II controlled substance orally or by way of electronic transmission other than electronic prescribing, provided that if the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call-back to the practitioner using the practitioner's phone number as listed in the telephone directory and other good faith efforts to insure his or her identity; and:
- 8.9.2.a. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period shall be pursuant to a prescription issued in the normal course of practice as authorized in subsection 8.9.1. of this rule.
- 8.9.2.b. the orally communicated prescription is immediately reduced to writing by the pharmacist, or, if necessary, the prescription communicated by way of electronic transmission other than electronic prescribing is immediately reduced to a hard copy;
- 8.9.2.c. within seven <u>fifteen</u> days after authorizing an emergency oral prescription, the practitioner delivers a valid paper or electronic prescription for the emergency quantity prescribed to the dispensing pharmacist. The practitioner may send the follow-up prescription to the pharmacy via facsimile, or take a photograph or scan of this follow-up prescription and send the photograph or scan to the pharmacy in place of the

paper prescription. It is the responsibility of the practitioner to ensure that, whichever method the practitioner uses, the prescription contains all of the required information outlined in 21 CFR 1306.05 and 1306.11(d), including the statement that the prescription is "Authorization for Emergency Dispensing." The prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the orally or electronically transmitted prescription. The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it shall be postmarked within the seven fifteen day period; if sent by electronic prescription, it must be transmitted by the prescriber within the seven fifteen day period. Upon receipt, the dispensing pharmacist shall attach this written prescription to the emergency oral prescription which had earlier been reduced to writing or to the hard copy of the electronically transmitted prescription. The pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration and the Board if the prescribing practitioner fails to deliver a written prescription.

To summarize the changes now effective until the end of the State of Emergency:

- 1. The DEA reiterates that there is not a defined time for "amount adequate to treat the emergency." Please see further discussion on the DEA Guidance.
- 2. The practitioner must speak to the pharmacist. This cannot be done via an agent of the physician. (See 8.9.2 above)
- 3. The pharmacist must get an "original" prescription within FIFTEEN days, instead of the original seven.
- 4. The "original" may come in one of four methods to be filed with the verbal prescription by the pharmacist:
 1) paper prescription with a wet signature mailed within 15 days 2) sent via fax 3) sent as a photograph 4) sent as a scan
- 5. The prescribing practitioner is responsible for ensuring that all of the information is on the prescription, including "Authorization for Emergency Dispensing" and maintaining the original prescription.

19. An APRN has come into my pharmacy telling me that she has the ability to prescribe Schedule II medications. Is this permitted now?

Governor Justice has provided an Executive Order that permits <u>the Board of Nursing</u>, at their discretion, to temporarily suspend or modify the requirements for the authorization of prescriptive authority, prescriptive formulary limitations, prescriptive refill and supply limitations, and other prescriptive limitations.

Pursuant to the Governor's Executive Order 17-20 permitting the West Virginia Board of Examiners for Registered Professional Nurses, in their discretion, to temporarily suspend or modify the requirements for the authorization for prescriptive authority, collaborative requirements for prescriptive authority, prescriptive formulary limitations, prescriptive refill and supply limitations, and other prescriptive limitations including continuing education and renewal requirements, contained in W. Va. Code §30-7-15a, §30-7-15b, §30-7-15c), the Board suspends and modifies the requirements as follows:

- The advanced practice registered nurse shall practice in conformity with the advanced practice registered nurse's education, training, and certification and in accord with the delineation of privileges granted to the advanced practice registered nurse by the hospital/facility to use the advanced practice registered nurse to the fullest extent possible.
- o For West Virginia APRNs, who have been approved to practice in West Virginia during the State of Emergency, the requirement for collaborative agreements with physicians for the prescribing of medications is suspended and automatically reinstated when the declared emergency is lifted.
- For West Virginia APRNs with prescriptive authority, who have been approved to practice in West Virginia during the State of Emergency, Schedule II drugs of the Uniform Controlled Substances Act and antineoplastics, if the patient has been on these medications, are permitted to be refilled if the refill is required during the declared emergency. The prescribing physician's name must be written on the prescription as well as the last date the prescription was filled. The Board of Pharmacy requests the

- name of practitioner and prescription number of the original prescription the APRN is refilling. They suggest notifying that practitioner as well. The implementation date with the DEA is pending. The Board will announce the details when they become available.
- o For West Virginia APRNs with prescriptive authority, who have been approved to practice in West Virginia during the State of Emergency, the Drugs listed under Schedule III shall not be limited to a thirty day supply and are permitted to be refilled if the refill is required during the declared emergency.

20. How should we handle the certification of sterile compound areas and primary engineering controls (compounding hoods) during the COVID-19 pandemic?

The question has come up regarding the requirement of certification of sterile compounding areas and equipment when facilities are limiting access to outside vendors during the COVID-19 crisis. The Board will not require sterile compounding facilities to have their primary and secondary engineering controls recertified if they become due during the period of limiting outside exposure. However, we would expect the facilities to continue the required gloved fingertip and media fill testing. Also, if facilities have the means to incubate contact plates or paddles, surface sampling should be done weekly in the compounding rooms and primary engineering controls (hoods). All compounding staff must be cautioned that the need for impeccable aseptic technique is of paramount importance. Recertification may be rescheduled after the emergency status has been lifted; however, we know that there is the likelihood that a backlog will develop quickly. We will expect all facilities and PICs to do the best they can.

21. Is the WV BOP currently doing inspections?

Yes. The WV BOP has resumed regular inspections.

22. I saw the HHS announcement about pharmacists doing COVID-19 testing on 4/8/2020. Is this permissible in WV?

Questions regarding pharmacists doing COVID-19 testing can be found on the wvbop.com website here.

23. Where does the USP 800 enforcement stand with the WV BOP?

Because of significant shortages of PPE and construction limitations during COVID-10, the WV BOP has voted to delay enforcement of USP 900 standards until July 1, 2021.

24. Is there a new version of the WV Pharmacy Law Book?

Yes. The New 2020 WV Pharmacy Law Book is now available for free download at our website here.

Questions?

Pharmacists with immediate concerns or questions can contact the Director of Professional and Regulatory Affairs, Krista Capehart, at 304-206-5767.